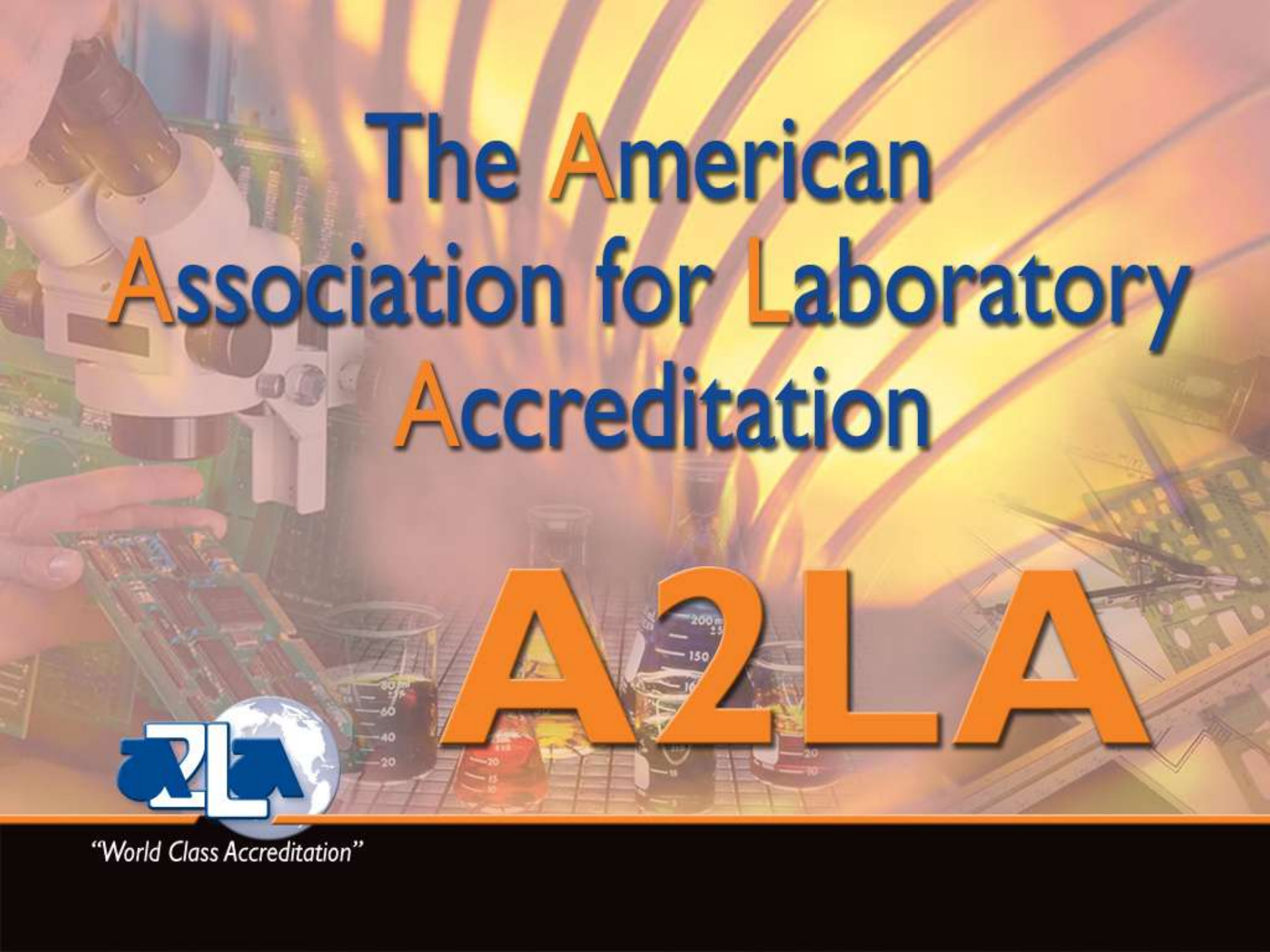
The American
Association for Laboratory
Accreditation
A2LA
"World Class Accreditation"

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What is A2LA?

American **A**ssociation for **L**aboratory **A**ccreditation

- Established in 1978
- Largest U.S. multi-discipline Conformity Assessment Body (CAB) Accreditation system
  - ***More than 2100 CABs currently accredited***
- Fourth largest system in the world
- Located in Frederick, MD

What is A2LA?

Mission

- Provide world-class accreditation and training services for testing and calibration laboratories, inspection bodies, proficiency testing providers, reference material producers and product certifiers. These and other future services should create stakeholder confidence in the quality, competence and integrity of all A2LA-accredited organizations and in their products and services.

What is A2LA?

- Over 30 years experience in using ISO Guides & Standards
- 40+ highly-talented staff
- Non-profit, non-governmental
- Public Service Membership Society
- Third-party accreditation body

A2LA Programs

- Laboratory Accreditation – testing and calibration (ISO/IEC 17025)
- Inspection Body Accreditation (ISO/IEC 17020)
- Proficiency Testing Providers (ISO/IEC 17043)
- Reference Materials Producers (ISO Guide 34)

A2LA Programs

- Product Certification Body Accreditation (ISO Guide 65)
- Medical Testing Laboratory Accreditation (ISO 15189)
- Laboratory quality & related training

A2LA Fields of Testing/Calibration

- Mechanical
- Chemical
- Environmental
- Construction Materials
- Electrical
- Geo-technical
- Information Technology
- Calibration
- Non-destructive
- Biological
- Acoustics & Vibration
- Thermal
- Medical
- Forensics

A2LA DoD ELAP Program

- All labs are assessed to ISO/IEC 17025:2005 as the base standard.
- In addition, the requirements of 2003 NELAC Chapter 5 and the DoD QSM version 4.2 are assessed.
- Finally, labs are assessed to A2LA policies including the Proficiency Testing Policy, Measurement Traceability Policy, and Advertising Policy.
- The result is an accreditation that meets the requirements of the ILAC MRA and is therefore mutually recognized.
- This also allows for other specifiers' requirements to appear on the same scope i.e. AOAC, CPSC, Kentucky UST…etc.

Assessor Training Requirements

- Assessors attend a 5-day training course on ISO 17025:2005 where they are instructed on the standard, how to write deficiencies, and A2LA staff expectations.
- Must pass an exam at the end of the 17025:2005 course to receive an assessor contract.
- Must be technical experts in their field and stay current on developments.
- Must be trained in NELAC requirements with a yearly refresher.
- Must attend an 8-hour DoD QSM training course and attend yearly refresher.

Assessor Evaluation

- A2LA staff reviews each assessor report for completeness and validity of cited deficiencies.
- The Accreditation Council has the opportunity to comment on the thoroughness of the assessment performed.
- Assessors are evaluated by A2LA staff during on site assessments on a regular basis.
- Assessors begin as technical assessors and must pass evaluations before they can become lead assessors.

DoD ELAP Labs in Progress

- 28 Labs have applied to be assessed to 17025:2005, 2003 NELAC Chapter 5, and the DoD ELAP requirements.
- 22 Labs have been accredited as of March 25, 2011.
- These include new applicants to A2LA and existing A2LA accredited laboratories seeking to expand their current Scopes to to include the DoD ELAP requirements.

Most Common 17025:2005 Deficiencies

- Total number of deficiencies = 544

Management System	Number of Deficiencies
4.3 Document Control	39
4.13 Control of Records	34
4.11 Corrective Actions	20
4.14 Internal Audits	22
4.15 Management Reviews	20

Most Common 17025:2005 Deficiencies

- Technical Requirements
  - 5.4 Test and Calibration Methods and Method Validation
  - 5.5 Equipment
  - 5.6 Measurement Traceability
- Number of Deficiencies
  - 61
  - 41
  - 25

A2LA Policy Deficiencies

- Policy
  - PT Policy (based on NELAC and DoD)
  - Traceability Policy
  - Advertising Policy
- Number of Deficiencies
  - 29
  - 10
  - 15

Most Common QSM Specific Deficiencies

- Number of QSM specific deficiencies = 72

- Section
  - D-13 LOD Determination and Verification
  - D-14 LOQ Establishment and Verification
  - Grey Box 31 Equipment Performance Checks and Verification
  - Appendices F and G (QC limits in particular)

Assessor Suggestions When Preparing for Assessment

- Be prepared: Be aware of all of the Grey Box requirements, including Appendices C and D.
- Have policies and procedures developed to meet the QSM requirements for DoD projects.
- Be sure you have completed an initial round of LOD/LOQ verifications for all analyte/method combinations you wish to have on your scope before you apply.
- Understand what method modifications (as defined in Grey Box 21) and the validation requirements of 5.4.5.2 and Appendix C3.
- Understand the difference between correction and corrective action.
- Perform a thorough internal audit prior to assessment.

Assessor Suggestions When Preparing for Assessment

- Make sure you have a summary or can generate easily the following data:
  - ☐ a. Laboratory determined DL.
  - ☐ b. Concentration of the spiked sample used to verify the LOD.
  - ☐ c. Result obtained from the analysis of the spiked sample for LOD verification.
  - ☐ d. Criteria used to determine the LOD verification was acceptable.
  - ☐ e. The laboratory quantitation limit.
  - ☐ f. Concentration of the spiked sample used to verify the LOQ.
  - ☐ g. Result obtained from the analysis of the spiked sample for LOQ verification.
  - ☐ h. Criteria used to determined the LOQ verification was acceptable.

Common Issues Noted by Assessors

- Laboratories not running quarterly verifications for LOQ and/or LOD
- Laboratories running 2 Continuing Calibration Verifications (CCVs) and selecting only one for use.
- Laboratories not meeting the LCS recovery requirements.
- Laboratories not checking the calibration of micro syringes before they are placed into service.

A2LA DoD ELAP Points of Contact

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Questions

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